APPARATUS AND METHOD FOR SELECTIVELY POSITIONING A DEVICE AND

MANIPULATING IT

<u>-</u>16

FIELD OF THE INVENTION

This invention relates generally to an apparatus and method of selectively positioning the apparatus, e.g., within a lumen. More particularly, this invention relates to a device and method for pulling a catheter along a wire; a device and method for moving a wire relative to a catheter, a device and method for pulling a catheter relative to a guiding catheter or any larger bore pipeline through which it is inserted; and a device and method for pushing or pulling a device on top of a guide wire or inside a guiding catheter.

BACKGROUND OF THE INVENTION

In many different applications of invasive and minimally invasive medicine there is a need to introduce catheters and other devices into the body, usually through open lumens or closed lumens, utilizing percutaneous entry.

Conventional procedures for the introduction of the devices and their controlled motion in the body usually utilize a force, either a manual force or a motorized force, applied from the outside of the patient to "push" the device to the target area. One shortcoming of introducing the device via a "push" operation, even when done on top of a guiding wire, is that this procedure often does not provide optimal tractability into a tortuous anatomy, e.g., the coronary arteries. In contrast, a "pull"

Express Mail No. 5098567614

operation in which a pulling device precedes the apparatus and

"pulls" it into place increases the tractability of the device

and reduces the likelihood that the device will get caught in a

4 curve of the lumen or cause trauma to the lumen.

Another problem is the need to push wires through occluded lumen sections that have a great resistance to such penetration. The fact that the wire is pushed from the outside may waste all the pushing energy in accessive loops with very little or none of the pushing energy actually reaching the tip of

15

6

the wire.

OBJECTS AND SUMMARY OF THE INVENTION

It is an object of this invention to provide a device and method for pulling a catheter along a wire.

It is another object of this invention to provide a device and method for pushing a wire relative to a catheter.

In yet another object of this invention to provide a device and method for pulling a catheter relative to a guiding catheter or any larger bore pipeline through which it is inserted.

It is a further object of this invention to provide a device and method for pushing or pulling a device on top of a guidewire or inside a guiding catheter.

It is still a further object of this invention to provide an apparatus and method for selectively positioning a device, e.g., a stent, an Intra Vascular Sound (IVUS) transducer,

an atherectomy device (both rotational and directional), pressure sensors, balloons, and pushing wires to open occlusions, by pulling rather than pushing these devices into place.

<u>-1</u>6

변17 분

血8 算

It is an object of this invention to provide an apparatus for disposing a device in the target area of a lumen, comprising: a cylindrically shaped motor attached to the device, the motor having a longitudinal bore, the motor provided with a motor friction area disposed within the longitudinal bore; a guide wire disposed within the longitudinal bore, the guide wire and the longitudinal bore sized and adapted to impart friction between the friction area of the motor and the guide wire in an amount sufficient to permit the motor to change position relative to the guide wire by crawling against the guide wire when the motor is energized.

It is another object of this invention to provide an apparatus for disposing a device in the target area of a lumen, comprising: a cylindrically shaped motor attached to the device, the motor having an outer surface, the motor provided with a friction area on the outer surface; a cylindrical guide tube having an outer surface and an inner surface defining a longitudinal bore, the outer surface of the motor and the inner surface of the guide tube sized and adapted to impart friction between the friction area of the motor and the inner surface of the cylindrical guide tube in an amount sufficient to permit the cylindrical motor to change position relative to the guide tube by crawling against the inner surface of the guide tube when the

1 motor is energized.

2

3

4

5

6

7

8

9

10

115

16

17 18 19

20

21

22

23

24

25

26

It is still another object of this invention to provide an apparatus for disposing a stent in the target area of a lumen, comprising: a catheter having a proximal end, a distal end, a longitudinal bore therethrough, and an expandable balloon disposed at the distal end; a cylindrically shaped motor disposed at the distal end of the catheter distal to the balloon, the motor having a longitudinal bore communicating with the longitudinal bore of the catheter, the motor provided with a motor friction area disposed within the longitudinal bore; a guide wire disposed within the longitudinal bore of the catheter and the longitudinal bore of the motor, the guide wire and the longitudinal bore of the motor sized and adapted to impart friction between the friction area of the motor and the guide wire in an amount sufficient to permit the motor to change position relative to the guide wire by crawling against the guide wire when the motor is energized.

It is another object of this invention to provide a method of disposing a stent in the target area of a lumen, comprising the steps of:

a) constructing an apparatus comprising: a catheter having a proximal end, a distal end, a longitudinal bore therethrough, and an expandable balloon disposed at the distal end; a cylindrically shaped motor disposed at the distal end of the catheter distal to the balloon, the motor having a longitudinal bore communicating with the longitudinal bore of the catheter,

- the motor provided with a motor friction area disposed within the
- longitudinal bore, a guide wire disposed within the longitudinal
- bore of the catheter and the longitudinal bore of the motor, the
- 4 guide wire and the longitudinal bore of the motor sized and
- 5 adapted to impart friction between the friction area of the motor
- and the guide wire in an amount sufficient to permit the motor to
- 7 change position relative to the guide wire by crawling against
- 8 the guide wire when the motor is energized;
 - b) advancing the guide wire to the target area;
- 10 c) securing the guide wire;
 - d) energizing the motor so that it advances along the guide wire to the target area to dispose the stent in the target area of lumen;
 - e) inflating the balloon to secure the stent in the target area of the lumen;
 - f) deflating the balloon; and
 - g) withdrawing the guide wire, motor, and catheter from the lumen.

It is yet another object of this invention to provide a method of disposing a stent in an obstructed target area of a lumen, comprising the steps of:

a) constructing an apparatus comprising: a catheter having a proximal end, a distal end, a longitudinal bore therethrough, and an expandable balloon disposed at the distal end; a cylindrically shaped motor disposed at the distal end of the catheter distal to the balloon, the motor having a

9

115

16

17 18 19

20

21

22

23

24

25

26



1	longitudinal bore communicating with the longitudinal bore of the
2	catheter, the motor provided with a motor friction area disposed
3	within the longitudinal bore, a guide wire disposed within the
4	longitudinal bore of the catheter and the longitudinal bore of
5	the motor, the guide wire and the longitudinal bore of the motor
6	sized and adapted to impart friction between the friction area of
7	the motor and the guide wire in an amount sufficient to permit
3	the motor to change position relative to the guide wire by

crawling against the guide wire when the motor is energized;

- b) advancing the guide wire to the target area;
 - c) securing the guide wire;

9

10

115

20

21

- d) energizing the motor so that the motor advances along the guide wire to the obstructed target area;
 - e) securing the catheter;
- f) energizing the motor so that the guide wire advances through the longitudinal bore of the motor and into the obstructed target area of the lumen;
 - g) securing the guide wire;
- h) energizing the motor so that the motor advances along the guide wire and disposes the stent in the target area of the lumen;
- i) inflating the balloon to secure the stent in the target area of the lumen;
- j) deflating the balloon; and
- 25 k) withdrawing the guide wire, motor, and catheter from 26 the lumen.

1 2 3 BRIEF DESCRIPTION OF THE DRAWINGS FIG. 1 shows an embodiment of the invention in which a 4 5 cylindrically shaped motor and a guide wire are utilized to dispose a device in the target area of a lumen; 6 FIG. 2 is a cross-sectional end view of the embodiment ³⁴ 8 of the invention shown in FIG. 1; 9 FIG. 3 shows an embodiment of the invention in which a cylindrical motor and a cylindrical guide tube are used to 10 dispose a device in the target area of a lumen; 11 12 13 13 14 FIG. 4 shows a cross-sectional side view of another embodiment of the invention shown in FIG. 3; FIG. 5 shows the tractability of a catheter that is **1**45 pulled through a curve in a lumen in accordance with the present **1**6 invention; **417** FIG. 6 shows the tractability of a catheter that is pushed through a curve in a lumen in a conventional manner; 19 FIG. 7 shows an embodiment of the invention used to 20 dispose a balloon expandable stent in the lumen of a blood 21 vessel; 22 FIGS. 8A to 8D shows an embodiment of the invention 23 used to clear an obstructed lumen; and 24 FIG. 9 shows an alternative embodiment of the



25

26

invention.

5

6

DETAILED DESCRIPTION OF THE INVENTION

Miniature Oscillating Ceramic Motors (OCM) are well known in the art and are disclosed in U.S. patent 5,453,653 to Zumeris the specification of which is incorporated herein by reference. These motors can be made very small and in any shape and they operate by contacting a surface in an amount sufficient to generate sufficient friction to permit the motor to "crawl" along the contacted surface and change its position relative to the contacted surface when the motor is energized. These motors can be adequately insulated to act in aqueous environments. Their small size and low energy level requirements make them especially suitable for use inside living organisms.

FIG. 1 is a lateral perspective of one embodiment of the invention and shows a cylindrical motor 1 having a longitudinal bore therethrough. A guide wire 2 is disposed within the longitudinal bore 5. FIG. 2 is a cross-sectional end view taken on line A-A of FIG. 1 and shows the cylindrical motor 1 having an outer surface 3 and an inner surface 4 defining a longitudinal bore 5. The inner surface 4 defining the longitudinal bore 5 is provided with a friction area 6 adapted to engage the guide wire 2. The longitudinal bore 5 and the guide wire 2 are sized and adapted so that when the motor 1 is energized the motor 1 will crawl along the guide wire 2, thus, changing its position relative to the guide wire 2. The direction of movement is controlled selectively by energizing



wires (not shown) connected to the motor 1. In one embodiment,

shown in FIG. 2, a biasing means, e.g., a leaf spring 7 is

3 utilized to bias the guide wire 2 against the friction area 6 of

4 the motor 1.

T15

6

FIG. 3 is a cross-sectional side view of another embodiment of the invention and shows a cylindrical motor 8 having an external surface 10 mounted within a guide tube 9 having and outer surface 11 and an inner surface 12. The external surface 10 of the motor 8 and the internal surface 12 of the guide tube 9 are sized and adapted so that the friction area 14 of the motor 8 contacts the inner surface 12 of the guide tube 9 and crawls along the inner surface 12 so as to dispose a device, e.g., an Intra Vascular Ultra Sound (IVUS) transducer, atherectomy device, or physiological sensor, (not shown) in the target area of a lumen. In an especially preferred embodiment, shown in FIG. 4, a leaf spring 13 is utilized to bias the friction surface 14 of the motor 8 against the internal surface 12 of the guide tube 9.

In another embodiment of this invention, shown in FIG. 7, a balloon catheter with a micro-motor disposed at the distal end is used to dispose an expandable stent in the target area of a lumen. FIG. 7 shows a catheter 15 having a proximal end 16, a distal end 17, and a longitudinal bore 18 therethrough. An expandable balloon 19 is disposed at the distal end 17. A cylindrically shaped motor 1 is disposed at the distal end 17 of the catheter 15 distal to the balloon 19. The motor 1 has a

longitudinal bore 5 communicating with the longitudinal bore 18 of the catheter 15 and is provided with a motor friction area 6 disposed within the longitudinal bore 5 of the motor 1. A guide wire 2 is disposed within the longitudinal bore 18 of the catheter 15 and the longitudinal bore 5 of the motor 1. The guide wire 2 and the longitudinal bore 5 of the motor 1 are sized and adapted to impart friction between the friction area 6 of the motor 1 and the guide wire 2 in an amount sufficient to permit the motor 1 to change position relative to the guide wire 2 by crawling against the guide wire 2 when the motor 1 is energized.

1

2

3

4

5

6

7

8

9

10

114

115

16

□7 □8 □19

20

21

22

23

24

25

26

In operation, an expandable stent 20 is secured to the balloon portion 19 of the catheter 15 and the guide wire 2 is placed into the bore 18 of the catheter 15. The guide wire 2 is then introduced into the lumen to be treated and is advanced by pushing it until it is near the target area. The guide wire 2 is then secured. The micro-motor 1 is then energized so that it crawls along the guide wire 2 which pulls the catheter 15 into the proximity of the target area to be treated. Because the catheter 15 is "pulled" into position as shown in FIG. 5, there is improved tractability and less kinking of the catheter 15, and, thus, reduced risk of trauma to the internal surface of the lumen than when the catheter is "pushed" into place using conventional procedures as shown in FIG. 6. The balloon 19 is then expanded to secure the stent 20 in the target area of the The balloon 19 is then deflated and the guide wire 2 and lumen. the catheter 15 are pulled out of the lumen using conventional

1 methods.

2

3

4

5

6

7

8

9

10

15

16

127 148 149

20

21

22

23

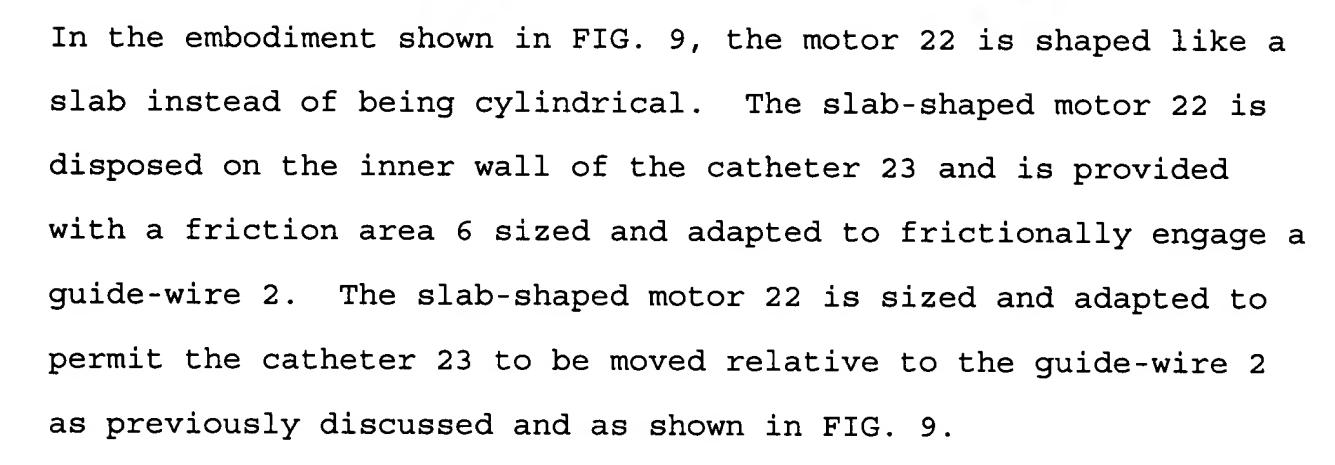
24

25

26

In another embodiment of this invention shown in FIGS. 8A to 8D, the motor is used to push the guide wire into, and if specific applications dictate through, a constricted area which clears the vessel of the obstruction to permit the catheter to advance beyond the obstruction to the target area. In operation, the catheter 15 is mounted on a guide wire 2 as previously discussed. The guide wire 2 is advanced to the obstruction 21 as shown in FIG. 8A. The guide wire 2 is secured and the motor is energized causing the catheter to advance towards the obstruction The catheter 15 is advanced until it too is in proximity to 21. the obstruction 21 as shown in FIG. 8B. The catheter 15 is then secured and the motor 1 is activated which causes the guide wire 2 to advance into the obstructed area 21 as shown in FIG. 8C. some applications, one or more passes may be utilized to clear the obstruction 21. The guide wire 2 is then secured, the motor 1 is energized, and the catheter 15 is advanced through the vessel past the area from which the guide wire 2 has cleared the obstruction 21 from the target area as shown in FIG. 8D. This method may be used to simply clear an obstruction in a lumen as discussed above or may be used in conjunction with other embodiments of the invention, e.g., to facilitate the placement of an expandable stent in the target area of a lumen by first clearing the target area of any obstructions.

FIG. 9 shows an alternative embodiment of the invention and shows a slab-shaped motor 22 incorporated in a catheter 23.



While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications, and other applications of the invention may be made.